



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,481	12/12/2003	Claus Garbe	WWELL73.008C1	2551
20995	7590	05/20/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			TONGUE, LAKIA J	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1645	

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,481

Applicant(s)

GARBE ET AL.

Examiner

Lakia J. Tongue

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 12-35, 40, 41, 46 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-11, 36-39 and 42-45 is/are rejected.
- 7) ☒ Claim(s) 7, 36-39 and 42-45 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11 and 36-47, drawn to a microbially active peptide, classified in class 530, subclass 326.
- II. Claims 12-35, drawn to a nucleic acid molecule, classified in class 536, subclass 23.4.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions can be used to accomplish different things. Peptides can be used in a materially different process to make antibodies and the nucleic acid can be used as a probe in a southern blot.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

In the event applicant elects Group I, claims 1-11 and 36-47 applicant is required to elect a single species. Claims 1-11 and 36-47 are generic to a plurality of disclosed patentably distinct species, which have different SEQ ID numbers and are structurally different, comprising:

- a) SEQ ID NO 1
- b) SEQ ID NO 2
- c) SEQ ID NO 3

In the event applicant elects Group II, claims 12-35 applicant is required to elect a single species. Claims 5-8 are generic to a plurality of disclosed patentably distinct species, which have different SEQ ID numbers and are structurally different, comprising:

- a) SEQ ID NO 1
- b) SEQ ID NO 2
- c) SEQ ID NO 3

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Marina Gordy on April 5, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-11 and 36-47. In addition a species election of SEQ ID NO. 2 was made. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-35, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

DETAILED ACTION

Claims 11-11 and 36-47 with the election of SEQ ID NO. 2 are under examination. Claims 5, 6, 40, 41, 46 and 47 have been withdrawn from consideration as they are drawn to a non-elected species. Claims 12-35 have been withdrawn from consideration as they are drawn to non-elected claims.

Priority

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action. Thus the examiner is affording the date of June 7, 2002 .

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 27, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Specification

This application fails to comply with the requirements of 37 C.F.R. 1.821-1.825 because it contains sequences that are not identified. For example, page 9, paragraph 0058 contain a sequence that are not identified. Appropriate sequence identifiers should match the sequence listing and the computer readable form (CFR) submitted with the application. Applicant is required to review the specification for unidentified sequences. Identification of these sequences is required.

Claim Objections

Claim 7 is objected to because of the following informalities: the claim should recite "residue" not residues. Appropriate correction is required.

Claims 36-39 and 42-45 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous

Art Unit: 1645

claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The above claims are the same as independent claims¹⁻⁴. Claim 36 does not further limit claim 1_A. ^{for example} There is nothing more than a peptide presented, thus showing that the claims are not further limiting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-11, 36-39, 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Akerblom et al (U.S. Patent 5,834,192).

Claims 1-4, 7-11, 36-39, 42-45 are drawn to an antimicrobially active peptide, wherein it comprises the DCD protein of SEQ ID NO: 1 or a DCD fragment preferably derived from the C-terminal region.

Akerblom et al disclose the protein DCD, which was identified in SEQ ID NO: 1. The expression of DCD in sweat glands was demonstrated using the dot blot method. Akerblom et al disclose a polynucleotide and amino acid sequence (SEQ ID NO: 2). SEQ ID NO: 2 is identical to the SEQ ID NO: 1 disclosed in the present application

(column 29-30). Moreover Akerblom et al disclose that modifications of the polypeptides include, but are not limited to acetylation, carboxylation, glycosylation, phosphorylation, lipidation and acylation. Post-translational processing which cleaves a "prepro" form of the protein may also be important for correct insertion, folding and/or function (column 11, lines 14-20). Additionally, Akerblom et al disclose that a fusion protein may be engineered to contain a cleavage site located between a HCAP sequence and the heterologous protein sequence (column 8, lines 42-48). Akerblom et al disclose that it can be designed with signal sequences in addition to other recombinant constructions (column 13, lines 14-20). Lastly, Akerblom et al disclose the use of the isolated protein in pharmaceutical compositions. Administration of the composition is accomplished orally or parenterally and can include topical delivery. Pharmaceutical compositions suitable for use in the present invention include compositions where the active ingredients are contained in an effective amount to achieve the intended purpose (column 22, lines 1-6). Inherently, the antimicrobially active peptide secreted from sweat glands is the same as the claimed composition because Akerblom et al disclose an identical peptide and amino acid sequence, which comprises SEQ ID NO: 1 and fragments thereof (SEQ ID NO: 2).

Claims 1-4, 7-11, 36-39, 42-45 are rejected under 35 U.S.C. 102(a) as being anticipated by Schitteck et al (Dermcidin: a novel human antibiotic peptide secreted by sweat glands, *Nature Immunology*, 2001; 2(12): 1133-1137).

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Olsen et al (U.S. Patent 6,420,116 B1) discloses antimicrobial peptides.

Selsted (U.S. Patent 6,008,195) discloses antimicrobial peptides and methods of use.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Claims 1-4, 7-11, 36-39, 42-45 are drawn to an antimicrobially active peptide, wherein it comprises the DCD protein of SEQ ID NO: 1 or a DCD fragment preferably derived from the C-terminal region.

Schittek et al disclose antimicrobial peptides. Schittek et al disclose that in sweat, a processed DCD 47-amino acid peptide was generated that shows antimicrobial activity (abstract). The 47-amino acid peptide of Schittek et al (Fig. 3, page 1135) is identical to the claimed SEQ ID NO: 2. The antimicrobial peptide is secreted from the sweat gland and the peptide comprises SEQ ID NO: 1 and fragments thereof (SEQ ID: 2). Schittek et al disclose that an analysis was used to identify amino acid 1-46 of the peptide to determine that the COOH-terminal sequence was V(I/L)DSV-COOH. This showed that the peptide represented a processed form of the DCD protein that encompassed 47 amino acids of its COOH-terminal part (page 1134). Inherently the claimed peptide would connect to a further peptide or protein to give a fusion protein. Figure 3 shows the signal peptide in italics (page 1135). Limitations such as pharmaceutical compositions and cosmetic compositions are being viewed as intended use.

Schittek et al disclose that the antimicrobial peptide was highly effective against bacteria and at 10µg/ml it killed 100% of the organism (page 1135). Inherently, the claimed composition would function as an antimicrobially active peptide. The composition is identical to the peptide and amino acid sequence of the instant application.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LJT


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600